PATENT

AMENDMENTS TO THE CLAIMS

Following is a complete set of claims as amended with this Response. This complete set of claims excludes cancelled claim 1 and includes amended claims 2, 4, and 6.

1. (Cancelled)

2. (Currently Amended) ~~The method of claim 1:~~ In an implantable medical device for implant within a patient, the device having a plurality of sensors and a control unit for processing signals from the sensors, a method performed by the control unit comprising:

receiving signals from the sensors representative of physiological parameters of the patient detected at sub-maximal exertion levels;

estimating the ventilatory response of the patient at maximum exertion based on the signals detected at sub-maximal exertion levels; and

controlling at least one function of the device based on the estimated ventilatory response;

wherein the step of receiving signals representative of physiological parameters of the patient includes the step of receiving signals representative of Heart Rate, Arterial Oxygen Saturation, Right Ventricular 0_2, Stroke Volume, Tidal Volume, and Respiration Rate; and

wherein the step of estimating ventilatory response includes the step of calculating

$$VR = (\text{Tidal Volume} - \text{Respiratory Rate}) / (\alpha \times (\text{Arterial } O_2 \text{ Saturation} - \text{Right Ventricular } O_2) \times (\text{Heart Rate}) \times (\text{Stroke Volume})).$$

3. (Original) The method of claim 2 wherein the coefficient α is about 1.14.

4. (Currently Amended) ~~The method of claim 1:~~ In an implantable medical device for implant within a patient, the device having a plurality of sensors and a control unit for processing signals from the sensors, a method performed by the control unit comprising:

receiving signals from the sensors representative of physiological parameters of the patient detected at sub-maximal exertion levels;

estimating the ventilatory response of the patient at maximum exertion based on the signals detected at sub-maximal exertion levels; and

controlling at least one function of the device based on the estimated ventilatory response;

wherein the step of receiving signals representative of physiological parameters of the patient includes the step of receiving signals representative of Heart Rate, Arterial Oxygen Saturation, Right Ventricular 0_2, Tidal Volume, and Respiration Rate; and

wherein the step of estimating ventilatory response includes the steps of inputting a Stroke Volume Constant and then calculating

$$VR = (\text{Tidal Volume} - \text{Respiratory Rate}) / (\alpha \times (\text{Arterial } O_2 \text{ Saturation} - \text{Right Ventricular } O_2) \times (\text{Heart Rate}) \times (\text{Stroke Volume Constant})).$$

5. (Original) The method of claim 4 wherein the Stroke Volume Constant is set to about 50 ml.

6. (Currently Amended) ~~The method of claim 1:~~ In an implantable medical device for implant within a patient, the device having a plurality of sensors and a control unit for processing signals from the sensors, a method performed by the control unit comprising:

receiving signals from the sensors representative of physiological parameters of the patient detected at sub-maximal exertion levels;

estimating the ventilatory response of the patient at maximum exertion based on the signals detected at sub-maximal exertion levels; and

controlling at least one function of the device based on the estimated ventilatory response;

wherein the step of receiving signals representative of physiological parameters of the patient includes the step of receiving signals representative of Heart Rate, Right Ventricular O_2, Stroke Volume, Tidal Volume, and Respiration Rate; and

wherein the step of estimating ventilatory response includes the steps of inputting an Arterial Oxygen Saturation Constant and then calculating

VR = (Tidal Volume - Respiratory Rate) /

(α x (Arterial O_2 Saturation Constant - Right Ventricular O_2)

x (Heart Rate) x (Stroke Volume)).

7. (Original) The method of claim 6 wherein the Arterial O_2 Saturation Constant is about 0.95.

8. (Withdrawn) The method of claim 1 wherein the step of estimating ventilatory response for the patient includes the steps of:

receiving signals representative of ventilation amplitude, ventilation rate, and sinus rate; and

determining ventilatory response by multiplying the ventilation amplitude by the ventilation rate and correlating with the sinus rate.

9. (Withdrawn) The method of claim 1 wherein the step of estimating ventilatory response for the patient includes the steps of:

receiving signals representative of the current level of activity of the patient, sinus rate and minute ventilation; and

determining ventilatory response by dividing minute ventilation by the current level of activity of the patient and correlating with the sinus rate.

10. (Withdrawn) The method of claim 1 further including the step of determining a value representative of a risk of mortality to congestive heart failure based on the estimated ventilatory response.

11. (Withdrawn) The method of claim 10 wherein the step of controlling at least one function of the device includes the step of comparing the value representative of risk of mortality with a threshold value and, if it exceeds the threshold value, controlling a telemetry device to output a warning signal.

12. (Withdrawn) The method of claim 10 further including the step of also determining a value representative of a risk of mortality to congestive heart failure based on heart rate reserve as a function of the exertion level of the patient based on signals received from the sensors.

13. (Withdrawn) The method of claim 12 further including the step of combining the value representative of a risk of mortality determined based on ventilatory response with the value representative of a risk of mortality determined based on heart rate reserve as a function of the exertion level to yield a single congestive heart failure mortality risk metric.

14. (Withdrawn) The method of claim 1 wherein the step of controlling at least one function of the device includes the step of controlling a memory device to store the estimated ventilatory response as diagnostic information.

15. (Withdrawn) In an implantable medical device for implant within a patient, a system comprising:

a plurality of physiological sensors; and

a ventilatory response estimation unit operative to estimate the ventilatory response of the patient at maximum exertion based on the signals detected by the physiological sensors at sub-maximal exertion levels.

16. (Withdrawn) The system of claim 15 further wherein the ventilatory response estimation unit is part of a congestive heart failure (CHF) risk determination unit operative to process signals from the sensors and to determine the risk of mortality to CHF for the patient.

17. (Withdrawn) The system of claim 16 wherein the CHF risk determination unit also includes a heart rate reserve estimation unit operative to determine heart rate reserve as a function of exertion level and to determine the risk of mortality to CHF based on both heart rate reserve and ventilatory response.

18. (Withdrawn) The system of claim 16 wherein the CHF risk determination unit is further operative to compare the risk of mortality with a threshold risk level and to generate a warning signal if the risk of mortality exceeds the threshold risk level.

19. (Withdrawn) The system of claim 15 wherein plurality of sensors comprise:
a heart rate detector, an arterial oxygen saturation sensor, a right ventricular 0_2 sensor, a stroke volume sensor, a tidal volume sensor, and a respiration rate sensor.

20. (Withdrawn) In an implantable medical device for implant within a patient, a system comprising:

means for determining that the patient is at a sub-maximal exertion level;

means for detecting one or more physiological parameters of the patient at the sub-maximal exertion level; and

means for estimating the ventilatory response of the patient at maximum exertion based on the signals detected at the sub-maximal exertion level.

21. (Withdrawn) The system of claim 20 further comprising means for determining a risk of mortality to congestive heart failure for the patient based on the estimated ventilatory response.

22. (Withdrawn) The system of claim 21 wherein the means for determining the risk of mortality to congestive heart failure comprises means for determining heart rate reserve for the patient as a function of exertion level and for determining the risk of mortality to CHF based on both heart rate reserve and ventilatory response.

23. (Withdrawn) The system of claim 22 wherein the means for determining the risk of mortality to congestive heart failure compares the value representative of risk of mortality with a threshold value and, if it exceeds the threshold value, generates a warning signal.

24. (Withdrawn) The system of claim 20 further comprising means for storing the estimated ventilatory response as diagnostic information.